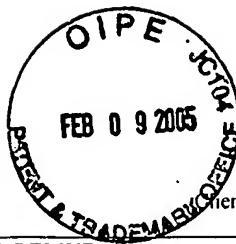


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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER WH-1 |
| INTERNATIONAL APPLICATION NO. PCT/IB2003/005197 | | U.S. APPLICATION NO. (if known) (37 CFR 1.5) 10/523999 |
| INTERNATIONAL FILING DATE 14 November 2003 | | PRIORITY DATE CLAIMED 5 December 2002 |
| TITLE OF INVENTION Process For the Extraction and Isolation of Insulin from Recombinant Source | | |
| APPLICANT(S) FOR DO/EO/US SAHIB Maharaj K, RAJU Edupuganti B, SHALIGRAM Umesh S | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | |
| Items 11 to 20 below concern document(s) or information included: | | |
| <ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A preliminary amendment. (2 pages). 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: Credit Card payment form. | | |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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|---|-------------------|---|----------------|---|--------------------------------|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) | | INTERNATIONAL APPLICATION NO. PCT/IB2003/005197 | | ATTORNEY'S DOCKET NUMBER WH-1 | |
| The following fees have been submitted | | | | CALCULATIONS PTO USE ONLY | |
| 21. <input checked="" type="checkbox"/> Basic national fee \$300 | | | | \$ | 300.00 |
| 22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) \$100 All other situations \$200 | | | | \$ | 200.00 |
| 23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared and provided to the Office \$400 All other situations \$500 | | | | \$ | 100.00 |
| TOTAL OF 21, 22 and 23 = | | | | \$ | 600.00 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| 29 - 100 = | 19 | 1 | x \$250 | \$ | 4750.00 |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)). | | | | \$ | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | 129 - 20 = | 109 | x \$50 | \$ | 5450.00 |
| Independent claims | 5 - 3 = | 2 | x \$200 | \$ | 400.00 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | + \$360 | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/3. | | | | | |
| SUBTOTAL = | | | | \$ | 6450.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | \$ | |
| TOTAL NATIONAL FEE = | | | | \$ | 6450.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | \$ | |
| TOTAL FEES ENCLOSED = | | | | \$ | 6450.00 |
| | | | | Amount to be refunded: | \$ |
| | | | | Amount to be charged: | \$ |
| <p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-3321. A duplicate copy of this sheet is enclosed.</p> <p>d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> | | | | | |
| <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> | | | | | |
| <p>SEND ALL CORRESPONDENCE TO:</p> <p>Dr. O.M. (Sam) Zaghmout Bio Intellectual Property Services (Bio Ips) LLC 8509 Kernon Ct. Lorton, VA 22079 Phone: 703-550-1968; Fax: 703-550-0409</p> | | | | | |
| | | | | SIGNATURE | Sam Zaghmout |
| | | | | NAME | Dr. O.M. (Sam) Zaghmout |
| | | | | REGISTRATION NUMBER | 51,286 |



10/523999

DT05 Rec'd PCT/PTO 09 FEB 2005

PATENT
WH-1

Patent Reference Number:

CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in
Washington, DC. 20231

on Feb. 09. 2005
(Date)

Typed or printed name of person signing this certificate

Dr. O. M. (Sam) Zaghmout
Signature Sam Zaghmout

Attachments: Listed below (4 items).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

SAHIB Maharaj K
RAJU Edupuganti B
SHALIGRAM Umesh S

**Title: PROCESS FOR THE EXTRACTION AND ISOLATION OF INSULIN FROM
RECOMBINANT SOURCES**

Filing Date:

Application Serial Number: /

Examiner:

Mail Stop: PCT

Honorable Commissioner for Patents
P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Attached herewith for filing is a 25-page patent specification including a 1 page sequence listing, 129 claims, and an abstract. Also included is Figure 1-4 on 4 sheets. The specification and the drawings constitute the application of Sahib et al. for the captioned invention.

This application claims the benefit of U. S. Provisional Application No. 60/431,050, filed December 5, 2002 ; International Patent Application No. PCT/IB2003/005197, filed November 14, 2003. The entire disclosure of these prior applications are hereby incorporated by reference.

In addition, the followings are attached:

1. PTO -1390 (2 pages)
2. Preliminary Amendment (2 pages)
3. A copy of the PCT/IB2003/005197
4. A credit card payment form (duplicate copies are attached).

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17 or credit any overpayment, to

deposit account No. 50-3321. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, or otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-3321.

Respectfully submitted,
Sam Zaghmout
O. M. (Sam) Zaghmout Ph.D
Registration No. 51,286

Contact Information:

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8509 Kernon Ct, Lorton, VA 22079. USA
Cell Phone (703-919-4348), Fax: (703-550-0409)
(703) 550-1968 (Voice/Fax)

DT07 Rec'd PCT/PTO 0-9 FEB 2005

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The PTO did not receive the following
listed item(s)

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